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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,596	01/21/2004	Michael C. Dean	4239-67289-01	6508

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,596	DEAN ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 13, 14, 15-18, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 25 are indefinite because an antibody fragment is not an antibody per se but a portion thereof. Also, it isn't clear if claims 15-18 are intended to encompass the full sequence recited or are intended to encompass partial sequences due to the conjunction "an". And lastly, the "at least" language in claims 13 and 14 is confusing. It seems to connote that some other particular but unspecified amino acid is encompassed within the recited epitope. Amendment of the claims to delete the "at least" would be remedial.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, and 13-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al. (US Patent 5,858, 719; filed July 17, 1997).

The claimed invention is drawn an antibody to SEQ ID NO:2 or SEQ ID NO:4, which are named ATP-binding cassette transporter-7 (ABC7) or human ATP-binding cassette transport protein (ABCtxH). The antibody is derived from a mammal or human. The antibody can be

monoclonal, polyclonal, or a fragment. The antibody can have a several detecting labels including a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, a phosphorescent compound, or an enzyme. Furthermore, the antibody is bound to a carrier including glass, polystyrene, polypropylene, polyethylene, dextran, nylon, amylase, cellulose, polyacrylamide, agarose, or magnetite. Moreover, in another limitation the antibody is coupled to a hapten including biotin, dinitrophenyl, puridoxal, or fluorescein. In addition, the antibody binds to an epitope including the amino acid 395 of SEQ ID NO:2 or SEQ ID NO:4 and can detect a mutation from an isoleucine to a methionine at the amino acid residue 395.

The antibody binds to a mutant ABC7 polypeptide, comprising the amino acid sequence of SEQ ID NO:4, expressed in a subject having or at risk for having X-linked Sideroblastic Anemia and Ataxia. The antibody detects the mutation of the isoleucine for methionine at the amino acid residue 395. The antibody can be monoclonal, polyclonal or a fragment. Finally, the antibody can be part of a kit for the detection of an ABC7 polypeptide.

Hillman et al. (U.S. Patent 5,858,719) teach an antibody to the polypeptide encoding the hABCtxH with 100% homology to SEQ ID NO:2 and 99.8% homology to SEQ ID NO:4 meeting the limitations of claims 1, 2, 3, 13-22. Since SEQ ID NO:2 and SEQ ID NO:4 are nearly identical except for the amino acid residue 395, an antibody binding to SEQ ID NO:2 will also likely bind to SEQ ID NO:4 despite the mutation. The antibody to the 2 polypeptides can be polyclonal, monoclonal, or an antibody fragment encompassing the limitations of claims 4, 5, 6, and 23-25 of this instant application (column 18, lines 16-22 and lines 37-47; column 19, lines 11-30).

In addition, Hillman et al. disclose a variety of protocols for detecting and measuring expression of the ATP binding cassette with antibodies. Examples include enzyme-linked

immunoabsorbent assay (ELISA), radioimmunoassay (RIA), and fluorescence activating cell sorting (FACS) (column 16, lines 12-24). Although Hillman et al. do not explicitly teach detectable labels, enzyme labels, radioisotope labels, and fluorescent labels are inherent to the ELISA, RIA, and FACS assays taught by Hillman et al.. These assays for measuring ATP binding cassette polypeptide are known in the art and provide a basis for diagnosing altered or abnormal levels of the protein. Normal or stand values for ABCtxH expression are established by combining body fluids. These recitations encompass the limitations of claims 20-22 (column 23, lines 52-55).

Moreover, Hillman et al. teach diagnostic assays for ABCtxH including methods utilizing the antibody and a label to detect ABCtxH in human body fluids or extracts of cells or tissues. The antibodies may be used with or without modification, and may be labeled by joining them, either covalently or non-covalently, with a reporter molecule. These teachings match the limitations of claims 26-28 disclosing a kit for the detection of the ATP binding cassette polypeptide with an antibody, which is labeled for detection (column 23, lines 44-51).

Thus claims 1-8 13-23-28 are anticipated by Hillman et al. (U.S. Patent 5,858,719).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. in view of Harlow et al. (1988).

Hillman et al. (U.S. Patent 5,858,719) teach an antibody to the human ATP binding cassette, which has 100% homology to SEQ ID NO:2 and 99.8% homology to SEQ ID NO:4, meeting the limitations of claims 1, 2, and 3. The antibody can be polyclonal, monoclonal, and fragments encompassing the limitations of claims 4, 5, and 6 of this instant application. Hillman et al. do not teach an antibody that is bound to a carrier or coupled to a hapten and do not explicitly teach the recited labels.

Harlow et al. (1988) recite methods for labeling an antibody for detection, for binding an antibody to a carrier, for coupling an antibody to a hapten.

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention was made to use the antibody taught by Hillman et al. binding to a polypeptide comprising an amino acid sequence in SEQ ID NO:2 or SEQ ID NO:4 because Harlow et al. recite a method for labeling an antibody for detection, for binding an antibody to a carrier, and for coupling an antibody to a hapten. Accordingly, the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
August 7, 2006

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